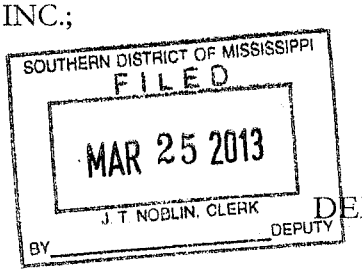
IN THE UNITED STATES DISTRICT COURT FOR THE
SOUTHERN DISTRICT OF MISSISSIPPI
JACKSON DIVISION

JEFFREY ALEX MEEKS — PLAINTIFF

V. — CIVIL ACTION NO: 3:13CV182 CWR-FKB

FRESENIUS MEDICAL CARE HOLDINGS, INC.;
FRESENIUS MEDICAL CARE NORTH AMERICA, INC.;
FRESENIUS USA, INC.;
FRESENIUS USA MANUFACTURING, INC.;
FRESENIUS USA MARKETING, INC.;
FRESENIUS USA SALES, INC; AND
JOHN DOE DEFENDANTS 1-5 — DEFENDANTS



COMPLAINT

(JURY TRIAL DEMANDED)

The Plaintiff Jeffery Alex Meeks by and through the undersigned counsel of record, files this complaint against Defendants, Fresenius Medical Care Holdings, Inc., Fresenius Medical Care North America, Inc., Fresenius USA, Inc., Fresenius USA Manufacturing, Inc., Fresenius USA Marketing, Inc., Fresenius USA Sales, Inc. ("Fresenius" or "Defendants"), and John Doe Defendants 1-5, and in support of the same states as follows:

INTRODUCTION

1.

This is a personal injury and products liability case which stems from injuries caused by dialysis treatments and products manufactured, sold and administered by the Fresenius Defendants. This case also arises from the Defendants' misrepresentations and concealment, wherein the Defendants concealed essential and ultimately harmful information regarding Fresenius dialysis products marketed under the names GranuFlo® and NaturaLyte®. This action

is brought by Plaintiff Jeffery Alex Meeks.

2.

Fresenius, a German company, is the largest operator of dialysis treatment clinics in Mississippi and the United States. Fresenius maintains forty-nine (49) dialysis clinics in the State of Mississippi alone. Fresenius is also a large distributor of dialysis treatment products, including dialysis equipment and dialysates such as GranuFlo® and NaturaLyte®, which Fresenius sells to non-Fresenius clinics, hospitals and dialysis providers throughout Mississippi and the nation. Dialysates are chemical agents used in screening the blood during the dialysis process. Dialysates contain a bicarbonate employed to offset the acid created by the failure of kidneys to purify the blood.

3.

GranuFlo® and NaturaLyte® have been implicated in a national epidemic of deaths of and serious injuries to dialysis patients. Fresenius knew or should have known that its products resulted in dangerously increased bicarbonate levels during treatment. Fresenius misrepresented and concealed said dangers, failing to provide proper protocols for medical providers to protect patients, and numerous cardiac events, such as suffered by the Plaintiff, and deaths were the direct result. Even though Fresenius knew or should have known of said dangers, Fresenius failed, for numerous years, to instruct medical providers about a safe protocol to protect patients against the extreme dangers posed by the serious increase in bicarbonate levels caused by GranuFlo® and NaturaLyte®. In June of 2012, the Food and Drug Administration ("FDA") announced a Class I recall of these dialysis products. The recall required Defendants to clarify instructions on their packaging because of improper use

resulting from unclear instructions. Defective design, inadequate warnings, and inadequate instructions led to serious patient complications, including sudden cardiac arrest, death, congestive heart failure, cardiopulmonary arrest, stroke, and other cardiovascular injuries.

4.

Even though Defendants knew or should have known of the dangers, medical providers were unaware that the high levels of bicarbonate resulting from the suggested use of the Defendants' products heighten the risk of cardiac injury by approximately six times. Furthermore, medical providers were never given a proper protocol to protect patients being treated with said products. As a result, thousands of patients receiving dialysis treatment were unknowingly overdosed. Even when Defendants finally began disclosing some of this information, they refused to protect all patients. For example, Fresenius issued an internal memo in 2011 disclosing the results of a study completed in 2010, but Fresenius failed to disclose such information to providers outside the Fresenius structure.

5.

Fresenius shared the internal memo with their own dialysis clinical staff only, not the thousands of others unknowingly using the products, which are unreasonably dangerous when used as directed. A copy of this memo was subsequently leaked to the FDA by an anonymous source, and Fresenius was contacted by the FDA on March 27, 2012. Two days later, Fresenius released a shorter, stripped-down, scientifically-vague, two-page memo to non-Fresenius clinics.

6.

Fresenius withheld critical information that could have prevented numerous heart attacks

and deaths. This preventable loss of life resulted directly from Defendants' refusal to conduct proper safety studies; defective product design; suppression of information revealing life-threatening risks; wanton failure to provide adequate instructions; and misrepresentations concerning the nature and safety of their products.

7.

Plaintiff, now 46 years old, began receiving dialysis treatments in 2009. On the first day of his dialysis treatments at a Fresenius clinic, Plaintiff returned home and suffered his first heart attack. After being taken to the hospital, the Plaintiff suffered another heart attack, had to be "brought back," and then suffered a third heart attack. He was then placed in the intensive care unit (ICU). During Plaintiff's treatment, Fresenius failed to instruct its employees on safe protocols or about the dangers associated with its products when used as directed. Plaintiff's heart attacks resulted from Fresenius's negligence and wrongful acts as described herein.

8.

This is a personal injury and products liability case action filed pursuant to the Mississippi Product Liability Statute, Miss. CODE. ANN. § 11-1-63, and other applicable Mississippi law. Causes of action are herein asserted against the Defendants for the wrongdoing alleged herein, and damages are sought for the Plaintiff.

PARTIES

9.

Plaintiff is Jeffery Alex Meeks, an adult resident citizen of Leflore County, Mississippi. Plaintiff suffered a massive myocardial infarction ("heart attack") in 2009 after receiving his first

dialysis treatment although Plaintiff had never had a problem with his heart prior to receiving the treatment. Plaintiff's condition resulted from the Defendants' products and misrepresentations, as specified herein.

10.

Defendant Fresenius Medical Care Holdings, Inc., doing business as Fresenius Medical Care North America ("FMCNA") is a corporation organized and existing under the laws of New York with its principal place of business located at 95 Hayden Avenue Lexington, Massachusetts 02420. FMCNA is the country's leading full-service provider of dialysis care. FMCNA, through various affiliates, treats approximately 79,600 patients in its approximately 1,080 U.S. dialysis clinics, many of which are located in this district. At all times relevant, FMCNA, regularly and continuously did business within and/or derived substantial revenue from business conducted within this judicial district.

11.

Defendant, Fresenius Medical Care North America, Inc. ("FMCNA") is a corporation organized and existing under the laws of Massachusetts with its principal place of business at 920 Winter Street Waltham, Massachusetts 02451. At all relevant times, FMCNA regularly and continuously did business within and/or derived substantial revenue from business conducted within this judicial district.

12.

Defendant, Fresenius USA, Inc. ("FUSA") is, and at all times herein mentioned was, a corporation organized and existing under the laws of Massachusetts. FUSA is a wholly owned subsidiary of Fresenius Medical Care Holdings, Inc. FUSA is a corporation organized under the laws of the Commonwealth of Massachusetts, with a principal place of business at 920 Winter

Street, Waltham, Massachusetts 02451. At all times relevant, FUSA regularly and continuously did business within and/or derived substantial revenue from business conducted within this judicial district.

13.

Defendant , Fresenius USA Manufacturing , Inc. ("Fresenius Manufacturing") is a corporation organized and existing under the laws of Delaware with its principal place of business at 920 Winter Street Waltham , Massachusetts 02451. At all relevant times, Fresenius Manufacturing was in the business of promoting, manufacturing, labeling, and distributing NaturaLyte® Liquid and GranuFlo® Acid Concentrates. Defendant does business throughout the United States and at all relevant times hereto, regularly and continuously did business within this judicial district. Fresenius Manufacturing is registered to do business within the State of Mississippi and may be served with process through service upon its registered agent, CT Corporation System, 645 Lakeland East Drive, Suite 101, Flowood, Mississippi 39232.

14.

Defendant, Fresenius USA Marketing, Inc. ("Fresenius Marketing") is a corporation organized and existing under the laws of Delaware with its principal place of business at 920 Winter Street Waltham, Massachusetts 02451. Fresenius Marketing regularly and continuously did business within this judicial district. Fresenius Marketing is registered to do business within the State of Mississippi and may be served with process through service upon its registered agent, CT Corporation System, 645 Lakeland East Drive, Suite 101, Flowood, Mississippi 39232.

15.

Defendant, Fresenius USA Sales, Inc. ("Fresenius Sales"), is a corporation organized and existing under the laws of Delaware with its principal place of business located at 920 Winter

Street, Waltham, Massachusetts 02451. Fresenius Sales is no longer registered to do business in the State of Mississippi, but at all relevant times conducted business within and/or derived substantial revenue from business conducted within this judicial district. At all relevant times herein, Fresenius was in the business of promoting, manufacturing, labeling, and distributing NaturaLyte® Liquid and GranuFlo® Dry Acid Concentrates. Defendant, Fresenius Sales does business throughout the United States and at all relevant times hereto, marketed, promoted, warranted and sold NaturaLyte® Liquid and GranuFlo® Dry Acid Concentrates in the State of Mississippi.

16.

John Doe Defendants 1 through 5 are individuals, corporate entities, holding companies, officers, directors, and/or others whose names and identities are unknown at this time, but will be disclosed by discovery in this action. Defendants John Does 1 through 5 conspired with and/or aided and abetted the Defendants, and participated in the planning, implementation and execution of, and/or knew or should have known of the course of wrongful conduct and breaches of duties alleged herein.

JURISDICTION & VENUE

17.

Jurisdiction is proper in this Court pursuant to 28 U.S.C. § 1332, as complete diversity exists among the parties and the amount in controversy exceeds Seventy Five Thousand Dollars ($75,000), exclusive of interests and costs.

18.

Venue is proper in this Court pursuant to 28 U.S.C. §1391, the general venue statute.

The Defendants are corporations subject to personal jurisdiction, doing business within this district and/or a substantial part of the events or omissions that give rise to the claims occurred in this district.

FACTS

I. PLAINTIFF SUFFERED A MASSIVE HEART ATTACK WITHIN HOURS OF RECEIVING A DIALYSIS TREATMENT AT DEFENDANTS CLINIC

19.

In 2009, at the time of his multiple heart attacks, the Plaintiff was a dialysis patient at a Fresenius medical clinic in Greenwood, Mississippi. Plaintiff underwent his first dialysis treatment, and after arriving home, Plaintiff suffered his first heart attack. Plaintiff went on to have two more heart attacks within the same 24-hour period of receiving a dialysis treatment from the Fresenius clinic. Prior to receiving said dialysis treatment from these Defendants, Plaintiff had never suffered a heart attack. Said heart attacks were the direct and proximate result of the negligence and wrongful conduct of these Defendants.

20.

Plaintiff's injuries, like those striking thousands of similarly situated victims across Mississippi and the country, were avoidable. If the Defendants had taken action to protect patients like the Plaintiff from known dangers, these unfortunate events would not have occurred. Fresenius negligently failed in its duties to the Plaintiff and wrongfully concealed from him the dangers, injuries and harm, including death, which might result from their treatments.

II. THE FRESENIUS PRODUCTS & PROTOCOLS RESULT IN CARDIAC ARREST AND/OR DEATH

21.

Fresenius is the largest operator of dialysis treatment clinics in Mississippi and the United States. Fresenius treats roughly one-third of U.S. dialysis patients at its clinics. Fresenius maintains forty-nine (49) clinics in the State of Mississippi, said presence in Mississippi being one of the largest *per capita* of any state. Fresenius has a vertically integrated business that owns thousands of dialysis clinics, and manufactures the machines and nearly all the products used in dialysis treatment such as dialyzers, bloodlines, needles, and dialysis concentrate. Fresenius is also a major distributor and seller of dialysis treatment products- including dialysis equipment as well as chemical agents including NaturaLyte® and GranuFlo® – and said products are sold to non-Fresenius dialysis centers and hospitals around the country.

22.

Dialysis is required for many patients in Mississippi suffering from kidney failure. Acid is a byproduct of metabolism in the body. The kidneys normally excrete this acid. Patients whose kidneys do not function properly, however, are unable to do this. As a result, they are at risk of developing a condition called acidosis, a buildup of excess acid in the blood. Physicians prescribe dialysis to correct this by neutralizing or buffering excessive acid through bicarbonates.

23.

A bicarbonate is an alkaline, i.e., a base, the opposite of an acid. Bicarbonate levels used in dialysis are slightly higher than normal blood levels to encourage diffusion into the blood. The bicarbonate acts as a pH buffer and neutralizes patients' acidosis.

24.

The bicarbonate levels within patients receiving dialysis must be controlled carefully to ensure their pH level remains stable. If it rises too high, patients develop "alkalosis" or "acidosis," both of which are very dangerous. Alkalosis, for example, is a significant independent and additive risk factor associated with cardiopulmonary arrest. In part, settings and readings on the dialysis machines control and monitor these levels during dialysis treatment.

25.

Proper dialysis treatment accomplishes the proper balance of bicarbonate delivery through use of a solution called dialysate. Dialysate is a mixture of three components, including bicarbonate concentrate and acid concentrate. All bicarbonate-based dialysis products deliver additional buffering capacity through mixing and metabolism of acetate, acetic acid, or citric acid when mixed for dialysate. Acetate, however, is unique.

26.

The liver quickly converts acetate to bicarbonate. During dialysis involving use of dialysate that contains acetate; therefore, patients receive bicarbonate from two sources- the bicarbonate concentrate and the acid concentrate. This combination of the converted bicarbonate from the acetate, and the bicarbonate from the bicarbonate concentrate, results in what is called "total buffer." Excessive total buffer can cause alkalosis.

27.

Dialysis machines display a "bicarb value." That value, however, is not the total buffer; it only indicates the bicarbonate concentrate. Thus, the bicarbonate from the acetate is not

included in the machine displays. Additional calculations are necessary to determine the total buffer and account for the actual full amount of bicarbonate that a patient receives from a specific dialysate.

28.

The FDA regulates dialysate products as medical devices. Without sufficient testing and while disregarding various safety signals, the Defendants introduced a new product to the market as a Class II medical device by gaining clearance from FDA through its 510(k) process. A 510(k) pre-market notification is an application submission to FDA to obtain clearance to market a medical device. Within it, a company must demonstrate that its device is at least as safe and effective, that is, substantially equivalent, to a pre-existing legally marketed device. Defendants submitted their 510(k) pre-market notification to FDA (K030497) in early 2003 to introduce NaturaLyte®/GranuFlo® Dry Acid Concentrate. FDA cleared it on May 20, 2003. Defendants' product contains acetate, sodium diacetate specifically.

29.

A different reaction occurs when the acid used to form dialysate is sodium diacetate. Sodium diacetate is composed of equal parts of acetic acid and sodium acetate. When it combines with bicarbonate to make dialysate, the acetic acid consumes an equal amount of bicarbonate and produces an equal amount of acetate, a bicarbonate precursor, so that the amount of bicarbonate remains the same. Sodium acetate, however, does not consume an equal amount of bicarbonate and instead enters the bloodstream and reaches the liver, which metabolizes it thereby increasing the amount of bicarbonate delivered during dialysis above

the prescribed amount. When one accounts for the additional bicarbonate from this acetate after the body converts it, Defendants' formulation dangerously increases the total buffer ultimately delivered by the dialysate nearly twice as much as any other marketed product.

30.

The result of the Defendants' protocols, or lack thereof, for administering NaturaLyte® and GranuFlo® is bicarbonate overdose. Bicarbonate overdose poses a substantial risk of serious health consequences, including sudden cardiac arrest and/or death, congestive heart failure, cardiopulmonary arrest, stroke, and other catastrophic cardiovascular injuries. Multiple heart attacks, such as sustained by the Plaintiff are also results of elevated bicarbonate levels such as generated by the Defendants products and protocols for administering the same.

III. DEFENDANTS CONCEALED THE DANGERS & FAILED TO PROVIDE SAFE PROTOCOLS TO PROTECT DIALYSIS PATIENTS

31.

As set out above, Defendants' product significantly increased patients' total buffer and thus bicarbonate levels. Despite the risks of causing alkalosis and therefore sudden cardiac arrest, and without conducting proper testing and research studies, Defendants aggressively promoted their products in Mississippi and across the country.

32.

Defendants actively misled the consumers of their products, especially when used with their equipment under the protocols adopted by Fresenius. Defendants consistently misrepresented the high bicarbonate levels their product produced and the increased buffer levels

associated with its use in the information they provided to physicians, nurses, dialysis clinic staff, and patients. Such misrepresentations were either grossly negligent or willfully made. Without the benefit of the critical information described herein, including proper product labeling, warning, and instruction, dialysis treatments were rendered in an unsafe and dangerous manner. Defendants could and should have prevented the dangers to their patients, and to other consumers of their products, but they knowingly and/or willingly failed to do so.

33.

By at least 2003, Defendants knew, or should have known:

a. that patients using their product were developing post-dialysis alkalosis;

b. that alkalosis is a significant independent and additive risk factor associated with cardiopulmonary arrest, and leads to other metabolic imbalances that contribute to cardiac arrest;

c. that the major cause of alkalosis in dialysis patients was inappropriately high
dialysate total buffer concentration; and

d. that physicians needed warnings and adequate instructions to properly treat patients and prescribe the product, and staff needed adequate instructions regarding proper machine settings and proper review and monitoring of patients.

34.

A 2004 study published in the American Journal of Kidney Diseases titled, "Association of Predialysis Serum Bicarbonate Levels with Risk of Mortality and Hospitalization in the Dialysis Outcomes and practice Patterns Study" further informed Defendants of the well-known risk of elevated bicarbonate levels. The article identified the correlation between patients with increased pre-dialysis metabolic alkalosis levels were more likely to experience a heart attack or sudden cardiac death absent lowering the bicarbonate prescription.

35.

In a patent application Defendants filed on or about May 17, 2006, Defendants noted the "contribution of bicarbonate [in dialysis treatment] resulting from metabolism of acetate contained in an acid dialysate constituent." The patent application included a diagram of machine settings for GranuFlo® use that clearly showed the extra contribution of bicarbonate to the overall buffer. Therefore, Defendants knew as early as 2006, if not before, that its dialysate product required special instructions to the users in order to reduce the risk of dangerously high bicarbonate levels in patients.

36.

Between 2003 and 2012, Defendants repeatedly learned of persistent confusion about the bicarbonate settings on dialysis machines and physicians' prescriptions for bicarbonate. In particular:

a. Defendants knew, or should have known, that nephrologists, dialysis nurses and technicians, physicians, and patients were not properly educated, trained, or informed about the acetate levels in their dialysis concentrates and that their product significantly increased the total buffer;

b. Defendants knew, or should have known, that dialysis machines displayed a bicarbonate value that did not reflect an accurate total buffer value and therefore additional calculations and steps were necessary to achieve the proper level of bicarbonate;

c. Defendants knew, or should have known, that because of their misleading product information and inadequate warnings and instructions, patients were receiving too much bicarbonate, which could cause alkalosis;

d. Defendants knew, or should have known, that bicarbonate-induced alkalosis could cause a dialysis patient's blood pressure to plummet, which, independently or compounded with other metabolic disturbances, can lead to cardiac arrest and stroke; and

e. Defendants knew, or should have known, that the major cause of alkalosis in

dialysis patients was the aforementioned inappropriately high dialysate total buffer concentration.

37.

Thus, Defendants knew, or should have known, they had to warn about the risks and instruct users to account for them when ordering and administering patients' dialysis, and to take additional steps to assure patients received the proper treatments rather than dangerous doses of bicarbonate. Defendants' willful misconduct prevented all this from happening.

38.

By at least January 2011, Defendants had analyzed data and found that 941 patients from 667 facilities within Fresenius clinics had cardiopulmonary arrests, six times as many as that of competing products. Defendants knew that the high bicarbonate levels related to their product was an independent risk factor contributing to these deaths.

39.

Even after January 2011, when the clinical crisis was irrefutable, Defendants continued providing misleading information about the recommended protocols, products and equipment. Based on information and belief, there was collusion involving individuals in several Fresenius departments and organizations to hide, mislead, and obscure information and data from patients and consumers about the serious patient safety hazards associated with the use of the Defendants' products and equipment to maintain market share and minimize legal risks. Hence, the Defendants' conduct and wrongdoing described herein was within the knowledge of its officers, directors and managing agents.

40.

Finally, on or about November 4, 2011, Defendants internal staff prepared a memo

detailing Fresenius's negligent conduct and the injuries related thereto. Said Internal Memorandum is attached hereto as ***Exhibit A***. *Exhibit A*, or some portions thereof, were distributed internally within the Fresenius clinic network; however, Defendants provided no warning or instruction to competitor dialysis clinics that used Defendants' products and dialysis machines. Even when the causal relationship between the use of Defendants' products and conduct and the increased risk of alkalosis and cardiopulmonary arrest was inescapable, Defendants only provided this information and urgent medical recommendations to their own physicians and clinics. Fresenius's customers who used the same equipment and products in the manner recommended by Fresenius were left in the dark and continued to employ the dangerous protocol which Fresenius had abandoned.

41.

Some of the critical information contained in Exhibit A includes the following: The memo admitted "that alkalosis is a significant risk factor associated with cardiopulmonary (CP) arrest in the dialysis unit, independent of and additive to the risk of CP arrest associated with pre-dialysis hypokalemia" and that the major cause of metabolic alkalosis in dialysis patients "[wa]s inappropriately high dialysate total buffer concentrate." It admitted that Defendants' product was associated with increased serum bicarbonate levels and alkalosis, as well as the increased possibility of cardiopulmonary arrests. It "strongly recommended" certain instructions "[i]n light of these troubling findings." It directed that this dangerous issue "needs to be addressed urgently." Despite the life-threatening risks described in *Exhibit A*, Defendants wantonly withheld this information for months from the thousands of non-Fresenius physicians and clinics that were using their products, exposing thousands of people to known risks.

42.

In early 2012, *Exhibit A* was leaked to the FDA. On or about March 27, 2012, Fresenius received an inquiry from the FDA about the risks associated with its products and its practices. On or about March 29, 2012, the Defendants transmitted a memorandum to clinics and physicians outside the Fresenius system. Said Fresenius memorandum provided information regarding the "[r]isk of Alkalosis with acetate containing dialysis acid Concentrates" to some customers. An "urgent product notification" explained that Defendants' "products contain acetate (NaturaLyte® Liquid 4.0 mEq/L; GranuFlo® powder 8.0 mEq/L of acetate in the final dialysate); which in addition to bicarbonate, combine to yield the total prescribed buffer." It instructed that, "[t]otal buffer should be considered in addition to bicarbonate as part of writing the dialysis prescription." This warning about the "urgent" need to monitor bicarbonate levels and adjust prescriptions to avoid the risk of cardiac arrest and death came long after Fresenius knew or should have known about these risks. Moreover, the 2-page memorandum submitted to Fresenius's "outside customers" contained far less actionable information than *Exhibit A*, which was submitted only within the Fresenius system. Fresenius, at every turn, concealed the nature and consequences of the dangerous conditions resulting from its products and its protocols, to the detriment of the Plaintiff and other patients in Mississippi and throughout the United States.

IV. THE FDA RECALL

43.

On or about June 27, 2012, the FDA issued a Class I Recall of NaturaLyte® and GranuFlo® Dry Acid Concentrate. As part of the Recall, the FDA informed health care providers and the public that Defendants were cautioning clinicians to be aware of the concentration of acetate in Defendants' products, which might cause serious injury, including

death. The FDA warned that "[i]nappropriate prescription of these products can lead to a high serum bicarbonate level in patients undergoing hemodialysis. This may contribute to metabolic alkalosis, which is a significant risk factor associated with low blood pressure, hypokalemia, hypoxemia, hypercapnia and cardiac arrhythmia, which, if not appropriately treated, may culminate in cardiopulmonary arrest." Finally, the FDA noted that "[t]his product may cause serious adverse health consequences, including death."

44.

Only as a result of the FDA investigation and recall, Defendants finally began "enhancing" the labeling of their dialysate product and hemodialysis machine operator's manuals. Defendants' feeble efforts as described herein fell well short of the required warnings, practices and instructions necessary to address the grave safety risks their products presented. Because Defendants wantonly provided inadequate training and instruction regarding these risks, the amount of bicarbonate that patients actually received was dangerously or even lethally high. Indeed, such bicarbonate overdose resulted in the heart attacks of the Plaintiff. As a result of Fresenius's conduct, as described herein, physicians and staff erroneously believed their patients were receiving an appropriate dosage of bicarbonate, when in fact their patients were receiving extremely high doses of bicarbonate resulting in overdoses causing the health consequences described herein above.

45.

As a direct and proximate result of the Defendants' conduct as described herein thousands of patients, including the Plaintiff, received bicarbonate overdoses. It appears that Defendants' negligent conduct described herein persisted for nearly a decade. Had the

Defendants employed proper protocols and warnings, the Plaintiff would not have suffered three heart attacks in a 24-hour period shortly after receiving a hemodialysis treatment from Fresenius using these drugs.

CAUSES OF ACTION

COUNT I: NEGLIGENCE

46.

The Plaintiff incorporates, adopts by reference and realleges each and every allegation of this Complaint the same as though specifically set out herein again.

47.

At all relevant times, Defendants knew or reasonably should have known that their product was unreasonably dangerous and defective when used as designed and directed. A reasonably careful search and review of the scientific literature and other information, and proper research and testing, indicated:

a. that health care professionals were unaware that Defendants' product contained acetic acid, acetate, or citrate that converts to bicarbonate;

b. that as a result, the potential existed for Defendants' product to contribute to metabolic alkalosis;

c. that metabolic alkalosis was associated with a higher risk of cardiac injury and death in hemodialysis patients; and

d. that health care professionals needed adequate warnings and instructions to consider the impact of Defendants' acid concentrate on the dialysate buffer and adjust prescription practices, dialysis machine settings, and related dialysis treatment practices.

48.

Defendants had a duty to exercise reasonable care, and to comply with the then existing standard of care, in the design, testing, research, development, packaging, distribution, promotion, marketing, advertising, instruction, and sale of their product. Specifically:

a. Defendants had a continuing duty to ensure that the product they provided was safe and used correctly through proper design, testing, research, adequate instruction, post-market surveillance, and appropriate modifications;

b. Defendants had a duty to anticipate the environment in which the product would be used and to design against the reasonably foreseeable risks attending the product's use in that setting, including misuse or alteration;

c. Defendants had a continuing duty to give an adequate warning of known or reasonably foreseeable dangers arising from the use of their product;

d. Defendants had a duty to provide adequate warnings and instructions, which means they had to be comprehensible to the average user, calculated to convey the material risks to the mind of a reasonably prudent person, and of an intensity commensurate with the danger involved;

e. Defendants had a continuing duty to assure the product they provided was properly labeled and true to the representations Defendants made about it;

f. Defendants had a continuing duty to make sure their product had complete and accurate information and instructions concerning its proper use;

g. Defendants had a continuing duty to assure those writing and carrying out patients' prescriptions fully understood the nature, characteristics, and proper use of Defendants' product to allow them to communicate and effectuate the patients' medical needs safely, the proper dialysis machine settings, and safe treatment;

h. Defendants had a continuing duty to assure dialysis clinical staff were properly informed of and trained on proper use of Defendants' product and that they complied with said training;

i. Defendants had a continuing duty to modify their products, and their packaging, instructions, promotional and advertising efforts to eliminate confusion and user error, assure compliance, and prevent harm; and

j. Defendants had a continuing obligation to disseminate appropriate content and employ appropriate methods to convey accurate and complete product information.

49.

In violation of the existing standards and duties of care, Defendants, individually and collectively, deviated from reasonable and safe practices in the following ways, by:

a. designing a defective product in formulation and warnings/instructions;

b. failing to conduct pre and post market safety tests and studies;

c. failing to collect, analyze, and report available data regarding dialysis patients' use of Defendants' product;

d. failing to conduct adequate post-market monitoring and surveillance;

e. failing to include adequate warnings about and/or instructions concerning the increased risks of death and serious injury;

f. failing to provide adequate warnings and/or proper instructions regarding proper uses of the product;

g. failing to provide adequate warnings and/or proper instructions regarding monitoring dialysis patients before, during, and after dialysis;

h. failing to inform users that Defendants had not adequately tested or researched the product to determine its safety and risks;

i. failing to inform users that the clinicians, nurses, and/or physicians were not adequately trained, instructed, credentialed, and prepared for proper use of the product in a safe and effective manner;

j. failing to educate and instruct users about the unique characteristics of their product and the proper way to administer it and operate the dialysis machines because of it;

k. failing to properly instruct staff regarding machine calibration; product preparation (e.g., specific gravity test); bicarbonate preparation; formula selection (e.g., machine entry); base sodium and bicarbonate (e.g., machine entry); and dialysate verification;

l. failing to properly select, train, instruct, supervise, and monitor product users and their employees, agents, servants, officers, directors, and clinical staff;

m. failing to implement and execute corrective and preventive actions to eliminate injuries resulting from errors within clinics caused by the dozens of possible dialysate formulas Defendants provided, which may lead to administration and human errors by nursing staff;

n. making material misrepresentations about the product's safety, nature, characteristics, and proper use; and continuing to promote and market the product

despite the foregoing failures.

The injuries and damages alleged herein were the reasonably foreseeable result of Defendants' conduct.

50.

Had Defendants undertaken the tests, studies, and steps described herein, the injuries and damages complained of here would not have occurred.

51.

Defendants held themselves out as experts and specialists and therefore possessed a higher degree of skill and learning. Defendants had a special relationship with the medical providers and clinics involved such that they had a duty to control their behavior. Defendants had a special relationship with Plaintiff giving rise to the same duty.

52.

Defendants are bound for the care of their agents, servants, employees, officers, and directors and for the neglect and fraud of the same. Defendants are liable for the conduct of their agents, servants, employees, officers, and directors committed in the course of their activities on behalf of and in furtherance of the company. Defendants are liable for their agents, employees, officers, and directors conduct attempting to advance Defendants' business. These persons acted within the scope of those efforts and their employment, as applicable. They were not exercising any independent business, but rather subject to Defendants' immediate direction and control. Defendants retained the right to direct or control the time and manner of executing the work, and interfered and assumed control with it. Defendants expressly and impliedly authorized and ratified the conduct of their agents, servants, employees, officers, and directors. Defendants received significant benefits as a direct result of their agents', employees', servants', officers', and directors' conduct.

53.

Defendants' conduct showed willful, malice, wantonness, oppression, or that entire want of care that raises the presumption of conscious indifference to consequences. Defendants' wrongdoing constitutes gross negligence, and said gross negligence proximately caused the damages of Plaintiff.

54.

As a direct and proximate result of Defendants' conduct and omissions described herein, Plaintiff's life was dramatically affected by putting his health in a worse condition than it was before the dialysis treatment. Further, Defendants' actions have further decreased the Plaintiff's overall enjoyment of quality of life. Plaintiff's health condition has also affected those around him by depriving them of Plaintiff's previous capacity to function at the same physical, mental, and emotional levels in his relationships with them and increasing their caretaking duties toward him. Plaintiff has also had an increase in medical, and other necessary expenses incurred as a result of Defendants' misconduct.

COUNT II: NEGLIGENT MISREPRESENTATION

55.

The Plaintiff incorporates, adopts by reference and realleges each and every allegation of this Complaint the same as though specifically set out herein again.

56.

Defendants had a duty to exercise reasonable care to those to whom they provided product information and to all those relying on the information provided. Defendants were

aware of the uses to which the information was being put, including foreseeable persons such as Plaintiff and his medical providers and the clinic staff.

57.

In violation of the existing standards and duties of care, Defendants, individually and collectively, in the course of their business and for pecuniary gain, negligently misrepresented, failed to disclose, and concealed material facts concerning the nature, character, quality, safety, and proper use of their product. Defendants knew, or reasonably should have known, that those express and implied representations were false under the circumstances.

58.

In violation of the existing standards and duties of care, Defendants, individually and collectively, materially misrepresented and omitted complete and accurate information in their product's labeling, advertising, marketing, sales and marketing persons, seminars, presentations, publications, notices, oral promotional efforts, websites, product information, training, and clinical forms, including acknowledgment of risks and informed consent forms. Defendants concealed information that the product was associated with an increased risk of serious injury and/or death. Defendants concealed that the product was not as safe as alternatives. Defendants failed to exercise reasonable care of competence in obtaining or communicating truthful and accurate information. Defendants failed to exercise reasonable care in obtaining or furnishing information for others' guidance. Defendants failed to discover the falsity of the representations they made. Defendants acted, and failed to act, with the intent to defraud, deceive, and mislead. At no time relevant here, did Defendants correct the misinformation provided.

59.

The Plaintiff reasonably relied upon Defendants' expertise, skill, judgment, and knowledge

and upon their express and/or implied warranties that their product was safe, efficacious, adequately tested, administered by properly instructed persons, of merchantable quality, properly formulated, and fit for dialysis use. Plaintiff justifiably relied upon the misrepresentations and omission described here, and reasonably believed them to be true. In justifiable reliance upon these misrepresentations, Plaintiff was induced to use Defendants' product.

60.

Had Defendants not made express and implied false statements, or revealed all material information about the product, Plaintiff would not have used the product and his medical providers would not have administered it.

61.

Defendants' conduct showed willful misconduct, malice, fraud, wantonness, oppression, or that entire want of care that raises the presumption of conscious indifference to consequences. Defendant's conduct was malicious, willful, wanton, reckless, and, at the very least arose to the level of gross negligence so as to indicate a wanton disregard of the rights of others.

62.

Defendants' conduct directly and proximately caused the injuries and damages sustained by the Plaintiff, as described herein.

COUNT III: PRODUCT LIABILITY

63.

The Plaintiff incorporates, adopts by reference and realleges each and every allegation of this Complaint the same as though specifically set out herein again.

64.

The Plaintiff hereby asserts a design defect claim pursuant to the Mississippi Product Liability Statute, Miss. CODE. ANN. § 11-1-63, and other applicable Mississippi law.

65.

At all times relevant to the Complaint, the Fresenius Defendants were in the business of designing, manufacturing, marketing, testing and distributing dialysis products. The product at issue was defective and unreasonably dangerous at the time it left the hands of the Defendants. Defendants placed their product into the stream of commerce in a defective and unreasonably dangerous condition such that the foreseeable risks exceeded the benefits associated with the design and/or formulation of the product.

66.

Defendants designed their product differently from preexisting products resulting in an unreasonably dangerous and defective product. According to Defendants, "bicarbonate-based dialysis products deliver additional buffering capacity through mixing and metabolism of acetate, acetic acid or citric acid when mixed for dialysate;" however, only Defendants' product delivered excessive acetate and significantly and unprecedentedly increased the total buffer. The liver quickly converts acetate to bicarbonate in the liver. This can contribute to metabolic alkalosis, which can cause dialysis patients' blood pressure to plummet leading to cardiac arrest and stroke. The cause of bicarbonate-induced alkalosis in dialysis patients was Defendants' inappropriately high dialysate total buffer concentration.

67.

Defendants' product was unreasonably and dangerously defective beyond the extent

contemplated by ordinary users with ordinary knowledge regarding these products. Plaintiff and his health care providers were unaware of the danger as Defendants provided ineffective and inadequate warnings and instructions, at best, and deliberately misled them.

68.

Defendants' product was defective due to inadequate post-marketing warnings and instructions, and/or inadequate testing and studies, and/or inadequate reporting regarding the results. Defendants' product was defective due to inadequate post-marketing warnings or instructions because, after Defendants knew or should have known of the risks, they failed to provide adequate information to the medical community and patients, but continued to promote the product as safe and effective.

69.

Defendants' product was defective in light of the dangers posed by its design and the likelihood of those avoidable dangers. Defendants' product was defective because the inherent risk of harm in Defendants' product design outweighed the utility or benefits of the existing product design. Defendants' product was defective because reasonably cost-effective and feasible state-of-the-art alternatives existed at the time that would not have undermined the product's usefulness.

70.

Defendants were aware of effective substitutes for the product, including their own alternative concentrates and dialysis machine enhancements. The gravity and likelihood of the dangers posed by the product's design outweighed the feasibility, cost, and adverse consequences to the product's function of a safer alternative design that Defendants reasonably should have

adopted.

71.

There was a safer alternative design that would have prevented or significantly reduced the risk of injury. It was reasonable as well as economically and technologically feasible at the time the product left Defendants' control by the application of existing or reasonably achievable scientific knowledge.

72.

Defendants failed to comply with industry standards, including federal or state safety standards and regulations, and industry-wide customs, practices, and design standards. Defendants' noncompliance with such standards demonstrates the product design selected was unreasonable considering the feasible choices of which Defendants knew and should have known. Despite any instances of compliance with such standards, Defendants' product still contained a design defect.

73.

The defective and unreasonably dangerous conditions discussed herein existed when the product left Defendants' control. They existed when Defendants sold the product. They existed when Plaintiff received it.

74.

Defendants' conduct showed willful, malice, wantonness, oppression, or that entire want of care that raises the presumption of conscious indifference to consequences.

75.

As a direct and proximately result of the design defect and the Defendants' conduct alleged herein, Plaintiff suffered damages for which a cause of action is hereby stated.

COUNT IV: FAILURE TO WARN

76.

The Plaintiff incorporates, adopts by reference and realleges each and every allegation of this Complaint the same as though specifically set out herein again.

77.

The Plaintiff hereby asserts a failure to warn/instruct claim pursuant to the Mississippi Product Liability Statute, MISS. CODE. ANN. § 11-1-63, and other applicable Mississippi law.

78.

Defendants' product was defective due to inadequate post-marketing warnings and instructions, and/or inadequate testing and studies, and/or inadequate reporting regarding the results. Defendants' product was defective due to inadequate post-marketing warnings or instructions because, after Defendants knew or should have known of the risk of injury from their product, they failed to provide adequate warnings to the medical community and patients, and continued to promote the product as safe and effective. The dangers at issue were of the kind that required warnings and instructions. Said product was defective because it failed to contain adequate warnings or instructions.

79.

In part, Defendants failed to provide adequate warnings regarding the existence of additional acetate in their product that the body could convert to bicarbonate, which could cause metabolic alkalosis, a condition associated with a higher risk of cardiac injury and death.

Defendants failed to provide adequate instructions for health care providers to be aware of these risks, alter prescription practices, adjust the dialysis machines, and take other steps before, during, and after the dialysis treatment process to avoid these dangers. Any information Defendants provided about these risks was inadequate in content, presentation, and delivery. They were ineffective for those who would be foreseeably affected by the product. Defendants' product was capable of being made safe for its intended and ordinary use.

80.

Plaintiff and his providers were unaware of the dangers and proper instructions. Neither Plaintiff, nor his providers understood and appreciated the risks associated with the product or its proper usage. The dangers described herein were not known, obvious, or apparent. They did not result from any unforeseeable and unanticipated use. Defendants' conduct and internal memoranda support these allegations.

81.

Defendants' conduct showed willful, malice, wantonness, oppression, or that entire want of care that raises the presumption of conscious indifference to consequences.

82.

As a direct and proximately result of the failure to warn and the Defendants' conduct alleged herein, the Plaintiff suffered damages for which a cause of action is hereby stated.

COUNT V: BREACH OF EXPRESS WARRANTY

83.

The Plaintiff incorporates, adopts by reference and realleges each and every allegation

of this Complaint the same as though specifically set out herein again.

84.

The Defendants represented and warranted to the Plaintiff, the medical profession and the general public that GranuFlo® and NaturaLyte® were safe for use in dialysis treatment in accordance with the Defendants' protocols. As noted herein, the Fresenius Defendants went to great lengths, including nationwide marketing and concealment, to warrant the safety of its product. Said affirmation of fact or promise, as well as the description of the goods, became a part of the bargain, creating an express warranty pursuant to Mississippi law.

85.

GranuFlo® and NaturaLyte® did not conform to Defendants' express representations and warranties.

86.

At all relevant times, including during the period that Plaintiff received dialysis treatment, GranuFlo® and NaturaLyte® did not perform as safely as an ordinary consumer would expect when used as intended or in a reasonably foreseeable manner.

87.

At all relevant times, including during the period that Plaintiff received dialysis treatment, GranuFlo® and NaturaLyte® did not perform in accordance with the Defendants' representations.

88.

In deciding to purchase and use GranuFlo® and NaturaLyte®, Plaintiff, other consumers, and the medical community relied upon Defendants' express warranties.

89.

As a direct and proximate consequence, the Plaintiff suffered multiple heart attacks. Plaintiff hereby asserts a claim for breach of express warranty pursuant to the Mississippi Product Liability Act, Miss. CODE. ANN. § 11-1-63, and other applicable Mississippi law.

COUNT VI: BREACHES OF IMPLIED WARRANTIES OF MERCHANTABILITY & FITNESS FOR PARTICULAR PURPOSE

90.

The Plaintiff incorporates, adopts by reference and realleges each and every allegation of this Complaint the same as though specifically set out herein again.

91.

By designing, marketing, and selling the product at issue, the Fresenius Defendants, merchants for goods relating to dialysis, impliedly warranted to the Plaintiff that said product was merchantable and fit for ordinary use. The Fresenius Defendants also warranted that said goods were fit for the particular purpose of dialysis treatment of the Plaintiff.

92.

Defendants' product was not fit for the ordinary purpose for which such goods were used. It was unmerchantable when used as directed and defective in design, and the Defendants' failure to provide adequate warnings and instructions resulted in said product being unreasonably dangerous. Defendants' product was dangerous to an extent beyond the expectations of ordinary consumers with common knowledge of the product's characteristics, including Plaintiff and his medical providers.

93.

Defendants breached their implied warranties because the product was not safe,

adequately packaged and labeled, did not conform to representations Defendants made, and was not properly usable in its current form according to the labeling and instructions provided. The Defendants' breaches of implied warranties, pursuant to Mississippi law, proximately resulted in the damages sustained by the Plaintiff.

COUNT VII: FRAUDULENT MISREPRESENTATION

94.

The Plaintiff incorporates, adopts by reference and realleges each and every allegation of this Complaint the same as though specifically set out herein again.

95.

Defendants committed actual and constructive fraud. Defendants committed constructive fraud by acting contrary to legal or equitable duties, trust, or confidence upon which Plaintiff relied, and by failing to act, though they should have. Defendants' conduct constitutes constructive fraud because Defendants breached legal and equitable duties and violated their fiduciary relationships. Defendants committed actual fraud by misrepresenting material facts, on which Plaintiff and his health care providers acted.

96.

Defendants made misrepresentations by means including, but not limited to, advertisements, website statements, written and oral information provided to patients and medical providers, marketing materials, clinical forms, and statements contained in product literature and trainings.

97.

Defendants intentionally and knowingly provided false product information. By providing the product and in the materials Plaintiff's providers received prior to his dialysis use in 2009, Defendants represented that their warnings, instructions, training, and product information were complete and accurate. Defendants represented that the product could be used as instructed when in fact the formulation required additional calculations and machine calibrations. Defendants misrepresented the proper use, character, and formulation of their product as well as its quality and safety. Defendants represented that their product had the same total buffer and effect as alternative available products. Defendants identified the bicarbonate level in their concentrates as lower than it in fact was. On the day Plaintiff received dialysis and before then, Defendants similarly misrepresented the true nature, character, safety, and proper uses of their product.

98.

Defendants marketed the product by claiming and representing GranuFlo® was "[s]afe for ...patients and staff' and that using dry sodium diacetate made "GranuFlo the safest dry acid product."

99.

Accurate facts were reasonably available to Defendants, even in the absence of knowledge of the falsity.

100.

Defendants' corporate and product marketing efforts misrepresented the true nature of the company and its product. Defendants' slogan, "patient centered care" misrepresented safety and diligence in the product's design and delivery. Defendants represented on their website and

other mediums that they would "deliver the highest quality care with respect and compassion." Defendants represented on their website and via other mediums that they would "treat [Plaintiff] well-to help [him] feel better." Defendants represented on their website and via other mediums that they provided "technologically-advanced care." Even today, Defendants' website and product information continues to represent that GranuFlo® is safe for patients and staff and offers "superior clinical outcomes," despite the known risks and inadequate warnings and instructions.

101.

The product Plaintiff received was not safe, efficacious, adequately tested, of merchantable quality, properly formulated, of the nature and character described, or fit for dialysis use, as Defendants knew. Defendants were aware of the falsity of the representations they made, but acted with flagrant disregard and recklessness as to whether the truth or falsity might be inferred.

102.

The information Defendants misrepresented was material to Plaintiff's and his medical providers' decisions in using the product. Defendants intentionally made these material misrepresentations knowing they were false, deceptive, and misleading and they made them intending to defraud, deceive, and mislead. Defendants presented themselves as experts in the field on their website and in marketing, sales, product, and clinical materials. Plaintiff and his medical providers justifiably relied upon them and reasonably believed them to be true. In justifiable reliance upon them, they were induced to prescribe and use Defendants' product. Had Defendants not made these express and implied false statements about the product, Plaintiff would not have used the product and his medical providers would not have administered it.

103.

Defendants' fraudulent representations evidence flagrant, willful, and depraved indifference

to patient health, safety, and welfare. Defendants' conduct showed willful misconduct, malice, fraud, wantonness, oppression, and that entire want of care that raises the presumption of conscious indifference to consequences.

104.

As a direct and proximate result of Defendants' fraudulent misrepresentations and intentional concealment of facts, upon which Plaintiff reasonably relied, Plaintiff suffered injuries and damages as described with particularity herein.

COUNTVIII: FRAUDULENT CONCEALMENT

105.

The Plaintiff incorporates, adopts by reference and realleges each and every allegation of this Complaint the same as though specifically set out herein again.

106.

The Fresenius Defendants fraudulently concealed essential, life-and-death information with respect to GranuFlo® and NaturaLyte® by:

a. failing to include warnings and/or adequate warnings of the increased risks of death and serious injury associated with using GranuFlo® and NaturaLyte®;

b. failing to provide adequate and/or proper instructions regarding the proper use of GranuFlo® and NaturaLyte®;

c. failing to provide adequate and/or proper instructions regarding monitoring dialysis patients before, during and after dialysis when GranuFlo® and NaturaLyte® were used;

d. failing to inform Plaintiff that GranuFlo® and NaturaLyte ® had not been adequately tested to determine the safety and risks associated with using the products;

e. failing to inform Plaintiff and others of the dangers associated with GranuFlo® and NaturaLyte® in the products' labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and/or regulatory

submissions;

f. failing to inform Plaintiff of the risks associated with using GranuFlo® and NaturaLyte®;

g. withholding and/or concealing and/or downplaying the information and/or evidence that the products were associated with an increased risk of serious injury and/or death;

h. concealing through affirmative misrepresentations that GranuFlo® and NaturaLyte® were as safe, and/or safer than other similar products used in dialysis treatment;

i. concealing information about the safety of GranuFlo® and NaturaLyte® including information that the products were not safer than alternative dialysis products available on the market;

j. concealing from Plaintiff information, regarding the true safety and/or efficacy of the GranuFlo® and NaturaLyte®; and

k. concealing from Plaintiff that the clinicians, nurses, and/or physicians were not adequately trained, instructed, credentialed, and prepared for proper use of all GranuFlo® and/or NaturaLyte® hemodialysis products in a manner that was safe and effective.

107.

Defendants had sole access to material facts concerning the dangers and unreasonable risks of GranuFlo® and NaturaLyte®.

108.

The concealment of information by Defendants about the substantial risks of serious injury and/or death associated with GranuFlo ® and NaturaLyte® were intentional, and the representations made by Defendants were known by Defendants to be false.

109.

Defendants made the concealment of information and the misrepresentations about the products with the intent that doctors and patients, including Plaintiff, rely upon them.

110.

Plaintiff and many others, including other patients and non-defendant healthcare providers involved in providing dialysis treatments, detrimentally relied upon the misrepresentations and material omissions of the Defendants and were unaware of the substantial increased risk of serious injury and/or death associated with and/or caused by GranuFlo® and NaturaLyte®, which Defendants concealed from Plaintiff.

111.

Had Defendants not fraudulently concealed such information, GranuFlo® and/or NaturaLyte® would not have been used during the dialysis treatment provided to Plaintiff.

112.

As a direct and proximate consequence of Defendants' concealment and wrongful conduct described herein, Plaintiff suffered multiple heart attacks.

COUNT IX: CIVIL CONSPIRACY

113.

The Plaintiff incorporates, adopts by reference and realleges each and every allegation of this Complaint the same as though specifically set out herein again.

114.

The Fresenius Defendants did conspire with each other and/or the John Doe Defendants and/or other non-defendant parties and individuals in the conception, planning, adoption, execution and concealment of the breaches and tortious conduct at issue in this suit. Said parties did act, and continue to act, in combination with one another as alleged in this Complaint. The actions of the Defendants, John Doe Defendants and other parties and entities were taken for the purpose of accomplishing the tortious and unlawful purposes alleged herein and/or for the

purpose of accomplishing other lawful purposes by the tortious and unlawful methods herein alleged above.

115.

The Plaintiff has been damaged as a result of the unlawful and tortious actions by said Defendants and John Doe Defendants in combination with each other and other parties, and causes of action are hereby stated against the Defendants and John Doe Defendants for actual and punitive damages for civil conspiracy as a result thereof.

COUNT X: AIDING & ABETTING

116.

The Plaintiff incorporates, adopts by reference and realleges each and every allegation of this Complaint the same as though specifically set out herein again.

117.

The Fresenius Defendants and the John Doe Defendants and other parties and/or individuals gave substantial assistance or encouragement to Fresenius in the conception and creation of, in the implementation and execution of, and in the subsequent concealment and manipulation of the breaches and wrongful conduct alleged in this suit. By such actions, the Defendants and John Doe Defendants did knowingly and intentionally give substantial advice and on-going assistance and encouragement to the conduct itself and/or the scheme of tortious conduct and/or to conceal the same from the Plaintiff.

118.

The Plaintiff hereby states a cause of action against the Defendants and John Doe Defendants for actual and punitive damages for aiding and abetting to the damage of Plaintiff.

COMPENSATORY DAMAGES

119.

As a direct and proximate result of the conduct and breaches of the Defendants, as aforesaid, the Plaintiff, Jeffery Alex Meeks, suffered serious and permanent injuries and damages, for which compensation is required. Specifically, the Defendants' products caused Plaintiff Meeks to suffer multiple heart attacks within a 24-hour period which resulted in him being in a worse medical condition than before he began receiving dialysis treatments. As a result, Plaintiff has suffered significant pain and suffering and he will have to undergo continued medical treatment. The Plaintiff is seeking monetary damages from the Defendants to compensate the Plaintiff for the following elements of damage:

(a) Medical expense;

(b) Conscious pain and suffering;

(c) Mental anguish;

(d) Emotional distress;

(e) Loss of enjoyment of life

(f) Loss of wage earning capacity; and

(g) All other elements of damage pursuant to Mississippi law.

As a result of the aforementioned acts and/or omissions, the Defendants are liable for all elements of all losses, both economic and intrinsic, tangible and intangible arising from the Plaintiff's worsened medical condition, all of which were proximately caused by the acts and/or omissions of the Defendants.

120.

The Plaintiff reserves the right to prove the amount of damages at trial. The amount of

compensatory damages will be in an amount to be determined by the jury.

PUNITIVE DAMAGES

121.

As set forth herein above, Defendants' conduct exhibited gross negligence and a willful, wanton and reckless disregard for the safety of the Plaintiff and others, as well as fraud and deceit, constituting an independent tort. The Defendants engaged in misrepresentation and concealment of the dangers from the Plaintiff, as well as other patients, doctors and the public. As a result of said conducted alleged herein, Defendants are liable for punitive damages and attorneys' fees, all litigation expenses and associated costs of litigation, pre-judgment interest and other damages pursuant to the Mississippi Punitive Damages Statute, MISS. CODE ANN. § 11-1-65.

122.

In addition to compensatory damages, the Plaintiff seeks punitive damages against the Defendants based on willful, malicious, intentional and gross negligence by said Defendants. The conduct justifying an award of punitive damages includes, but is not limited to, the Defendants' willful, malicious, intentional and gross negligence, the fraudulent and/or negligent acts of misrepresentation and/or concealment, as well as other conduct described herein. The amount of punitive damages to be awarded is an amount to be determined by the jury.

123.

Plaintiff prays that punitive or exemplary damages be assessed against the Defendants in an amount sufficient to punish the Defendants for their wrongful conduct and to deter like conduct in the future, and to serve as an example and a warning to others, so as to deter others from engaging in a similar course of conduct and to encourage other companies to have due and proper regard for the rights and lives of dialysis patients, and to protect the general public from

future wrongdoing. Plaintiff prays that punitive damages be awarded in the appropriate amount to accomplish these purposes, taking into consideration the appropriate factors as set forth by Section 11-1-65 of the Mississippi Code Annotated and/or other law, including the degree of reprehensibility of the Defendants' conduct, harm likely to result from the Defendants' conduct, the duration of that conduct, the Defendants' awareness of the wrongfulness of such actions, and the Defendants' financial condition.

WHEREFORE, PREMISES CONSIDERED, the Plaintiff, Jeffery Alex Meeks, sues and demands judgment from the Defendants, Fresenius Medical Care Holdings, Inc., Fresenius Medical Care North America, Inc., Fresenius USA, Inc., Fresenius USA Manufacturing, Inc., Fresenius USA Marketing, Inc., Fresenius USA Sales, Inc., and John Doe Defendants 1-5, and respectfully requests an order from this Court awarding damages and compensation for the following:

a. An award of actual, consequential and incidental damages in such amounts as are sufficient to compensate in full the Plaintiff for the losses and damages actually incurred as a result of the Defendants' wrongdoing;

b. An award of punitive damages in an amount adequate to punish the Defendants and serve as an example to deter similar conduct in the future;

c. An award of the Plaintiffs costs and expenses incurred in connection with this action, including attorneys' fees, expert witness fees and all other costs herein;

d. An award of pre-judgment and post-judgment interest as the Court deems appropriate; and

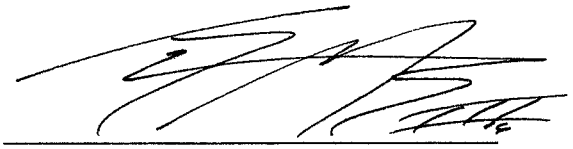
e. Granting such other and further relief as the Court deems just and proper, including restitution, imposition of a constructive trust and/or such extraordinary equitable or injunctive relief as permitted by law, equity or statutory provisions as

the Court deems proper to prevent unjust enrichment of the Defendants and to provide the Plaintiff with an effective remedy for the damages caused and injuries suffered as a result of the Defendants' wrongdoing as aforesaid.

JURY TRIAL DEMANDED

Respectfully submitted, this the 25th day of March, 2013.

JEFFERY ALEX MEEKS, PLAINTIFF



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